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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,509	11/09/2001	Graham E. Kelly	700136.405C1	5532

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/986,509	KELLY, GRAHAM E.	
	Examiner	Art Unit	
	John Pak	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-86* is/are pending in the application.

4a) Of the above claim(s) *33-72 and 81-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant is advised that the previous examiner of this application is no longer employed by the USPTO, and this application has recently been transferred to the undersigned Primary Examiner. In view of the long pendency of this application, applicant is invited to telephone the undersigned Examiner in the event that such course of action could expedite prosecution.

The following is noted to summarize prosecution history thus far. On 4/18/2003, a restriction requirement was made. On 10/8/2003, applicant elected with traverse the composition invention, wherein formononetin is combined with biochanin. Two terminal disclaimers have been filed and accepted: one over U.S. Patent 5,830,887 and another one over 09/602,191.

Claims 1-32 have been canceled. Claims 33-86 are pending. Claims 33-72 and 81-86 remain withdrawn from further consideration as being directed to non-elected subject matter. Claims 73-80 will presently be examined.

Effective Filing Date

Claims 73-80 were added on 12/23/2002, which is more than one year after the actual filing date of this application. In the submission of 12/23/2002, applicant argued that independent claim 73 finds descriptive support from, inter alia, specification page 9, lines 20-30 (emphases added):

Formononetin or daidzein are preferably administered to a subject substantially unaccompanied by other isoflavones. By this is meant that any composition or preparations may contain minor amounts of other isoflavones in the order of 10% (w/w) or less. Preferably the formononetin or daidzein represents at least 90% of isoflavone content, more preferably 95%, even more preferably 98% or more. Genistein, if present, is in amounts of about 5% or less, more preferably less than 1% (w/w) with regard to isoflavone content. It is recognised by regulatory agencies that an isoflavone content in the order of 95% of total isoflavones represents effective purity.

In the treatment of menopausal symptoms formononetin may be administered in combination with daidzein, for example from a ratio of 1:10 to 10:1.

Independent claim 73 does not specify the percentage of formononetin and does not specify the total percentage of other isoflavones.

The originally filed disclosure does not contain much in the way of formononetin + biochanin A (elected subject matter). Several inferences from the original disclosure must be made to arrive at the combination of formononetin + biochanin A. However, instant claim 73 further requires, "wherein the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less."

The only original disclosure of 10% w/w or less is with respect to the total amount of other isoflavones, as shown by lines 20-30 of specification page 9. The same can be said for 5% or less of genistein. In other words, the claim feature, "wherein the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less" was originally conveyed, if at all, with

respect only to compositions that contain 90% or more of formononetin. It is for this reason that the effective filing date of all the claims here, except claims 74-75, cannot be 5/1/1998, the filing date of the International application (PCT/AU98/00313). For lack of a better date, 11/9/2001 will be used for the purpose of this Office action as the filing date of claims 73 and 76-80. Effective filing date of claim 74 is 5/1/1998.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73 and 76-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As explained above, the 10% w/w limit on biochanin A and other isoflavone amounts were originally disclosed only with respect to formononetin that is “substantially unaccompanied by other isoflavones,” which is defined as containing 10% w/w or less of other isoflavones. Therefore, the feature of "wherein the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less” is new matter, which does not find adequate descriptive support from the originally filed disclosure.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 73-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/23069.

WO 93/23069 discloses a health supplement comprising a health supplementary amount of naturally occurring phytoestrogens selected from two or more of genistein, daidzein, biochanin A, formononetin, and/or their glycosides (claim 1). Claim 6 of this document shows the combination of biochanin A and formononetin. Further incorporation of dietary suitable excipient, diluent, carrier or food is disclosed (claim 2). Variety of health benefits are disclosed (page 8, last full paragraph). Foods such as soya that are high in phytoestrogens are associated with an alleviation of menopausal symptoms and hypocholesterolemic effects in humans (page 7, first full paragraph; page 17, first full paragraph). The product of the invention of WO 93/23069 is disclosed to modify or produce "reduced risk of development of many untoward symptoms (including dry vagina, peripheral flushing, depression etc) commonly associated in women with menopause" (see the paragraph bridging pages 15-16).

Because the methyl forms (biochanin A and formononetin) ultimately are largely demethylated to genistein and daidzein, with improved biological efficacy, "it is

unimportant whether the isoflavones are present in the claimed product in the methylated or demethylated forms" (page 10, lines 3-6). Leguminous plants such as soyabean are used as sources of phytoestrogens (paragraph bridging pages 10-11 & paragraph bridging pages 12-13). The hypocotyl of soya can be used as a source of phytoestrogens in order to reduce waste products, and the hypocotyl of soya contains 95% daidzein and 5% genistein, which can be used separately (page 12, line 16 to page 13, line 2; see Example 2 on pages 18-19 & Example 4 on page 20; claims 1, 4-5). Further, it is disclosed that "any source rich in phyto-oestrogens may be used instead, if desired" (page 9, line 1).

WO 93/23069 does not expressly disclose formononetin and biochanin A in a single specific exemplified combination. It goes without saying that 90-95% formononetin + 10% of less of biochanin A + any other isoflavone amount feature is also not expressly disclosed.

However, the teachings of WO 93/23069 is not so limited. The key teaching relevant to the instant application claims is that WO 93/23069 discloses the (1) the use of phytoestrogens from the hypocotyl of soya, which contains 95% daidzein and 5% genistein, and (2) the unimportance of whether the isoflavones are in their methylated or demethylated forms. Because daidzein and genistein are both demethylated forms (see page 9, chemical formulas), use of their methylated forms, i.e. formononetin and biochanin A, respectively, would have been obvious to the ordinary skilled artisan. WO

93/23069 teaches any source rich in phytoestrogens may be used and suggests the specific ratio of 95% formononetin and 5% biochanin A.

Various dependent claims recite or read on "if present" clause. Such a clause does not require anything. The claims have been so interpreted.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Applicant's argument relative to a previous ground of rejection that relied on WO 93/23069 has been given full consideration. It is noted though that said previous ground of rejection did not point out and rely on the teachings of this document wherein phytoestrogens from the hypocotyl of soya, which contains 95% daidzein and 5% genistein, can be used, and further that it is unimportant whether the isoflavones are in their methylated or demethylated form. Therefore, one having ordinary skill in the art would certainly have had reasonable expectation of success.

Applicant also argues WO 93/23069 teaches away from the claimed invention because the document emphasizes the importance of genistein's activities and deemphasizes the importance of formononetin. However, this argument is erroneous because soy hypocotyl containing 90% daidzein and 10% genistein is expressly disclosed and 15 subjects were administered this mixture and studied for various therapeutic effects (Example 4 on page 20). This goes against applicant's arguments

that WO 93/23069 deemphasized the importance of formononetin, because 90% daidzein (demethylated) suggests 90% formononetin (methylated), as clearly taught by WO 93/23069.

Applicant is advised that the obviousness type double patenting ground of rejection over 10/611,087 is hereby withdrawn in consideration of the claim feature in the instant application claims, "wherein the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less." As discussed above however, this feature constitutes new matter, so if and when this feature is deleted from the claims, applicant should expect reapplication of this double patenting ground of rejection.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616